**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **December 6, 2024**

# MONOPAR THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **001-39070** | **32-0463781** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (I.R.S. Employer Identification No.) |

| **1000 Skokie Blvd., Suite 350, Wilmette, IL** | **60091** |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

**(847) 388-0349**
Registrant's telephone number, including area code

**N/A**
(Former name or former address, if changed since last report)

**Securities registered pursuant to Section 12(b) of the Act:**

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| **Common Stock, $0.001 par value** | **MNPR** | **The Nasdaq Stock Market LLC (Nasdaq Capital Market)** |

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

**Item 7.01 Regulation FD Disclosure.**

On December 5, 2024, Monopar Therapeutics Inc. (Monopar) issued a press release announcing that a first patient was dosed with its Novel Therapeutic Radiopharmaceutical MNPR-101-Lu.

The press release is furnished as Exhibit 99.1 to this report and incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release Dated December 5, 2024 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Monopar Therapeutics Inc.**

Date: December 6, 2024

By: /s/ Karthik Radhakrishnan
Name: Karthik Radhakrishnan
Title: Chief Financial Officer

**Exhibit 99.1**

# Monopar Announces First Patient Dosed with its Novel Therapeutic Radiopharmaceutical MNPR-101-Lu

WILMETTE, Ill., December 5, 2024 — Monopar Therapeutics Inc. (Nasdaq: MNPR), a clinical-stage biotechnology company focused on developing innovative treatments for patients with unmet medical needs, today announced the first patient ever dosed with MNPR-101-Lu. This novel therapeutic radiopharmaceutical combines MNPR-101, Monopar's antibody that selectively targets the urokinase plasminogen activator receptor (uPAR), with the therapeutic radioisotope lutetium-177. uPAR is involved in tumor growth and metastasis, and is found in some of the most aggressive, deadly cancers, including pancreatic, ovarian, triple negative breast, and colorectal cancers.

The MNPR-101-Lu intravenous infusion was well-tolerated with no serious adverse reactions reported. This patient, dosed under a compassionate use protocol in the US, has metastatic pancreatic cancer, and prior to dosing, the cancer was imaged using MNPR-101-Zr (a zirconium-89 imaging radioisotope conjugated to MNPR-101) with a PET/CT scanner and showed uPAR expression.

"As a result of encouraging biodistribution and dosimetry clinical data we recently reported (link) with our radiodiagnostic, MNPR-101-Zr, we have been eagerly looking forward to initiating treatment of patients with MNPR-101-Lu, hopeful it may provide an important therapeutic benefit to a group of cancer patients very much in need," said Chandler Robinson, MD, Monopar's Chief Executive Officer.

"We are thrilled to have dosed this patient with MNPR-101-Lu, and believe this may be the world's first dosing of a patient with a uPAR-targeted therapeutic radiopharmaceutical," said Andrew Cittadine, Monopar's Chief Operating Officer.

Monopar is actively enrolling participants in two Phase 1 clinical studies in Australia, evaluating MNPR-101-Zr for imaging and MNPR-101-Lu for treatment of advanced solid tumors. Further information about the MNPR-101-Lu Phase 1a trial is available at www.ClinicalTrials.gov under study identifier **NCT06617169**. Further information about the MNPR-101-Zr Phase 1 imaging and dosimetry clinical trial is available at www.ClinicalTrials.gov under study identifier **NCT06337084**.

**About Monopar Therapeutics Inc.**

Monopar Therapeutics is a clinical-stage biotechnology company with ALXN-1840 for Wilson disease which has completed a Phase 3 trial, and radiopharma programs including Phase 1-stage MNPR-101-Zr for imaging advanced cancers, and Phase 1a-stage MNPR-101-Lu and late preclinical-stage MNPR-101-Ac225 for the treatment of advanced cancers. For more information, visit: www.monopartx.com.

**Forward-Looking Statements**

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Examples of these forward-looking statements include statements concerning: the MNPR-101-Lu intravenous infusion was well-tolerated with no serious adverse reactions reported; that as a result of recently reported encouraging biodistribution and dosimetry clinical data with Monopar's radiodiagnostic, MNPR-101-Zr, the Company has been eagerly looking forward to initiating treatment and to seeing if the Company can bring an important therapeutic benefit to a group of cancer patients very much in need; and the Company believes this may be the world's first dosing of a patient with a uPAR-targeted therapeutic radiopharmaceutical. The forward-looking statements involve risks and uncertainties including, but not limited to: that the patient may develop a serious adverse event in the future to MNPR-101-Lu; that radiation dosimetry analytics in the future may not be consistent with the estimated data generated thus far; that Monopar may not find enough patients to successfully enroll its MNPR-101-Lu therapeutic study; that the Phase 1 imaging and dosimetry clinical trial in advanced cancer patients with MNPR-101-Zr may not yield consistently satisfactory results; that future preclinical or clinical data may not be as promising as the data to date; that MNPR-101-Zr and/or MNPR-101-Lu may cause unexpected serious adverse effects or fail to be effective against the cancer tumors in humans; that the trials could result in a clinical hold should there be a Serious Adverse Event; Monopar's ability to raise sufficient funds in order for the Company to support continued clinical, regulatory and commercial development of its programs and to make contractual future milestone payments, as well as its ability to further raise additional funds in the future to support any future product candidate programs through completion of clinical trials, the approval processes and, if applicable, commercialization; uncertainties related to the regulatory discussions that Monopar intends to initiate related to ALXN-1840 and the outcome thereof; the rate of market acceptance and competitiveness in terms of pricing, efficacy and safety, of any products for which Monopar receives marketing approval, and Monopar's ability to competitively market any such products as compared to larger pharmaceutical firms; and the significant general risks and uncertainties surrounding the research, development, regulatory approval, and commercialization of imaging agents and therapeutics. Actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Monopar's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Monopar undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made. Any forward-looking statements contained in this press release represent Monopar's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

**CONTACT:**

**Monopar Therapeutics Inc.**
Investor Relations
Karthik Radhakrishnan
Chief Financial Officer
karthik@monopartx.com
Follow Monopar on social media for updates:
Twitter: @MonoparTx  LinkedIn: Monopar Therapeutics